Clinical Performance of a Rule-Based Decision Support System for Mechanical Ventilation of ARDS Patients

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ABSTRACT

We developed a clinical decision support system—ventilation protocols—that managed tidal volume and ventilator rate settings during mechanical ventilation of patients with the Adult Respiratory Distress Syndrome (ARDS). We applied these protocols for a total of 10,903 hours in 40 ARDS patients. The clinical staff suspended the protocols for only 5% of the total application time due to medical procedures, surgeries, transient clinical problems not addressed by the protocols, or because of attending physician request. Of 3,148 instructions generated by the ventilation protocols, the clinical staff followed 2,932 (93%). The staff did not follow some instructions because of patient data errors, computer software and protocol logic errors, inability of the clinical staff to implement protocol instructions because of more pressing duties, and clinical staff objections to specific instructions. Sixty percent of the patients treated by the ventilation protocols survived. Our results demonstrate that the ventilation protocols provided a practical and safe decision support system for the mechanical ventilation of ARDS patients.

INTRODUCTION

The Adult Respiratory Distress Syndrome (ARDS) is a syndrome of severe diffuse lung damage that results in very high mortality rates. Due to increases in lung stiffness and deterioration in lung function, almost all patients with fully developed ARDS require prolonged artificial respiratory support with a positive-pressure mechanical ventilator. However, when high concentrations of inspired oxygen or high airway pressures become necessary in a very ill patient, the ventilator itself may further damage the patient's lungs [1]. Ideally, a clinician should set the mechanical ventilator to optimize the tradeoff between too little ventilator support (low risk of ventilator injury but providing inadequate patient support) and too much ventilator support (high risk of ventilator injury). Unfortunately, the ideal ventilation strategy for ARDS patients is not known, with the published recommendations from different authors varying widely [2, 3].

We first became interested in clinical decision support systems for ventilator management when we developed protocols for the oxygenation of ARDS patients enrolled in a clinical trial [4, 5]. The oxygenation protocols were useful as a tool to insure equal intensity of oxygenation therapy in different treatment groups, thereby reducing variations due to individual treatment styles. However, we did not have protocols that provided recommendations for tidal volume and ventilator rate at that time, since the oxygenation protocols only recommended settings for fraction of inspired oxygen (F_IO_2) and positive end-expiratory pressure (PEEP). In this report, we describe the ventilation protocols we developed in the last two years to complement the function of the oxygenation protocols. Our goal was to develop a coordinated system able to provide complete decision support for ventilator management in ARDS.

From our experience with protocol implementation, we have discovered a number of benefits from protocol use. These benefits have provided the rationale for our continued development of clinical protocols. Before turning to a detailed description of the ventilation protocols, we will summarize four benefits of clinical protocol application.

In many clinical outcome studies, patient randomization with double blinding is adequate to control variations present in the patient population and the clinical environment. However, in studies that cannot be double blinded, the randomization process does not control both random and systematic (biases) variations introduced by the clinical staff *after* randomization. Computerized protocols always respond to a given clinical situation in the same manner, thus providing a tool for controlling post-randomization random and systematic variations in non-blinded clinical studies.

Clinical protocols are useful in providing a standard response to a given patient situation. Standardization of care may have some advantages in medicine, directly comparable to the known quality improvements in industrial settings which result from

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industrial process standardization and elimination of unnecessary variation [6].

Clinical protocols assist in the implementation of new clinical therapies. In ARDS, recent reports highlight the potential danger of high airway pressures used in conventional mechanical ventilation to promote further lung damage [1, 3]. Some authors have recommended lower airway pressures, even when this results in inadequate ventilation and in carbon dioxide accumulation [7]. The practice style in our intensive care has moved in the direction of minimizing airway pressures. The ventilation protocols have provided a method to implement these changes in a controlled fashion.

Finally, the process of developing clinical protocols is inherently educational. Precisely encoding otherwise vague clinical practices makes what is (and what is not) known explicit. A clear understanding of the deficits present in clinical knowledge provides the necessary basis for choosing further areas of research.

METHODS

Patient Selection:

We diagnosed ARDS in the LDS Hospital by prospective daily screening of all intensive care patients (according to Fowler's criteria, [9]). We excluded ARDS patients with active central nervous system disease and anti-depressant drug overdoses because of contraindications to hypercapnea and acidemia, respectively. We also excluded ARDS patients who were not intubated. Between February 8, 1992, and March 31, 1993, we attempted to manage all eligible patients with the ventilation protocols.

Protocol Development:

We implemented the ventilation protocols in the LDS Hospital HELP system. The HELP system [8] is a computer system which records and processes clinical data including laboratory data, x-ray reports, medication records, respiratory charting, and arterial blood gas reports. Our system operated in open-loop fashion, so that a protocol-directed action was the combination of a protocol recommendation and the subsequent acceptance and implementation of that recommendation by the clinical staff. An overview of ventilation protocol operation is shown in Figure 1.

Difficult patient management problems and clinical staff challenges to protocol logic provided stimuli for protocol refinement. A team approach was key in the development of the ventilation protocols. Clinical staff members often suggested general ideas for refinement of the protocols. Team members working with both the clinical and research staff members converted these ideas into explicit rules in the format of the ventilation protocols. A programmer having extensive experience in the implementation of clinical protocols then converted the rules into HELP-system programs. Physicians, nurses, and respiratory therapists provided ongoing feedback about

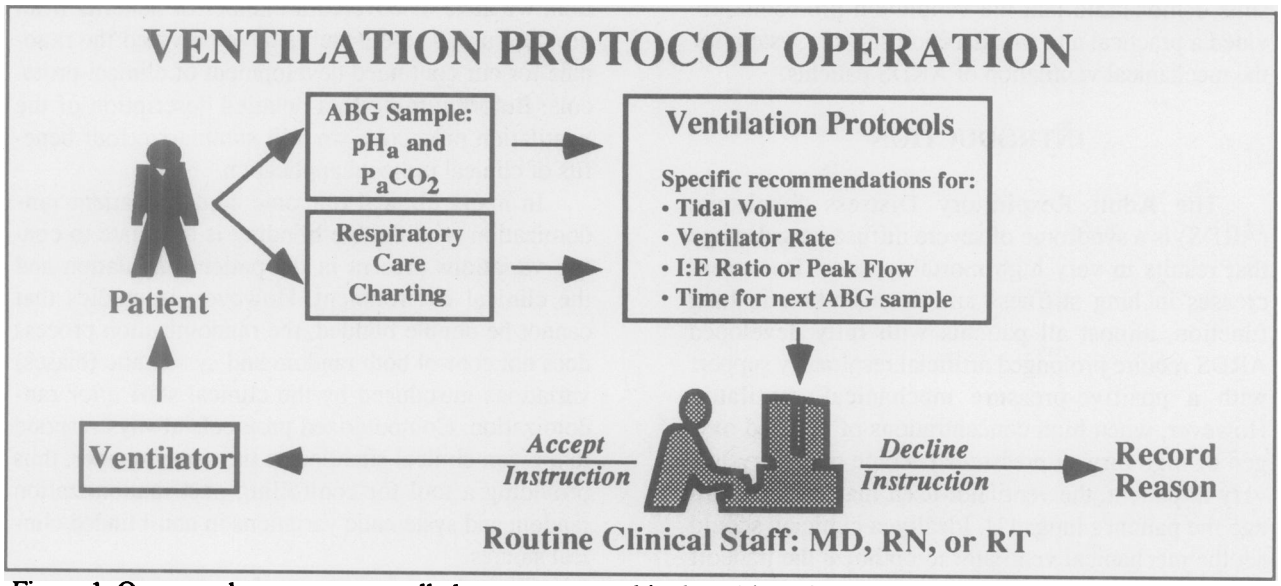

Figure 1. Our open-loop servo-controlled system operated in data-driven fashion, iteratively recommending ventilator adjustments in response to new patient data. The respiratory care charting contained values for the patient's current tidal volume, respiratory rate, and inspiratory pressures. ABG = arterial blood gas; pH_a = arterial pH; P_aCO_2 = partial pressure of arterial CO_2; I:E Ratio = ratio of inspiratory to expiratory cycle times; Peak Flow = ventilator inspiratory peak flow rate setting; MD = physician; RN = registered nurse; and RT = respiratory therapist.

the clinical appropriateness of the protocols. Proposals for changes could come from any member of the research or clinical staff. However, we required that all changes be based on objective patient data and that the changes reflect a consensus between the research and clinical teams.

Even though ARDS patients are critically ill, ventilator care for most of these patients proceeded in the standard manner encoded in the ventilation protocols. However, occasional ARDS patients had such unusual or severe problems that standard techniques were not adequate. We intended the protocols to address all common patient situations. However, it was not reasonable to cover situations that were unique to single patients. Our approach to protocol care in this circumstance was to suspend operation of the protocols: (a) until the patient returned to a more representative state, (b) until we modified the protocols to address the new situation, or (c) indefinitely if we considered the patient situation to be unique and poorly matched by the protocol logic.

The ventilation protocols underwent iterative development during the study period of February 1992 through March 1993. Although this necessarily resulted in protocols that changed somewhat during the study period, the basic rules described below remained stable. The protocol rules were secondarily dependent on airway pressures, which are not described further due to space limitations. We used a decrescendo inspiratory flow pattern and an inspiration to expiration ratio (I:E ratio) of 1:2.

We managed oxygenation (PEEP and F_IO_2 settings) with computerized protocols previously developed by our group [4].

Overview of Protocol Rules:

The ventilation protocols operated in two modes: *Controlled mode*, when the patient did not initiate ventilator breaths over a prolonged time; and *Assisted mode*, when the patient was able to initiate ventilator breaths.

In controlled mode, the protocols used an arterial pH (pH_a) goal of 7.30, with an acceptable pH_a range of 7.25 to 7.35. The tidal volume[1] goal was 6 mL/kg. When a patient entered controlled mode, the protocols always reduced the tidal volume to 6 mL/kg, by 2 mL/kg steps, provided that the patient's pH_a remained at or above 7.25. The patient's pH_a was adjusted by varying the number of ventilator breaths per minute (ventilator rate). As long as the pH_a remained above 7.25, the tidal volume remained at 6 mL/kg. If a patient's pH_a fell below 7.25 despite a maximum allowed ventilator rate (35 breaths per minute) the protocols increased the tidal volume stepwise up to a maximum of 10 mL/kg in order to increase the pH_a. We did not intend the ventilation protocols to provide primary treatment for metabolic acidosis, although the protocols recommended limited hyperventilation (maximum rate=35; maximum tidal volume=10 mL/kg) when the pH_a was below 7.25. Instead, metabolic acidosis was managed with the clinically appropriate non-ventilatory therapy.

In assisted mode, the patient's pH_a depended on how fast the patient initiated ventilator breaths, and was not controlled by the protocols. The protocols set a back-up ventilator rate to result in a calculated pH_a of 7.30 (the pH_a we calculated that the patient would have if the patient were to stop initiating ventilator breaths). The protocols increased the tidal volume stepwise up to 10 mL/kg if a patient initiated breaths at a rate above 35 breaths per minute, provided that the larger tidal volume was effective in reducing the patient's breathing rate.

Measurement of Protocol Performance:

We measured protocol performance in two ways. First, we determined the total number of hours of protocol application. Since it was sometimes necessary for clinical reasons (for example, the patient left the ICU for surgery) to suspend protocol operation temporarily, we determined the number of hours of protocol suspension and reasons for these suspensions. Second, we recorded the total number of instructions generated by the ventilation protocols as well as the number of these instructions that the clinical staff followed. For each declined instruction, the clinical staff provided a reason explaining why they did not follow that instruction.

RESULTS

We applied the ventilation protocols between February 8, 1992, and March 31, 1993. Figure 2 shows patient flow during the study.

We diagnosed ARDS in a total of 51 patients. We excluded ventilation protocol use in 5 ARDS patients because of the following reasons: Central nervous system disease (3 patients); anti-depressant drug overdose (1 patient); and patient never intubated (1 patient). Five patients were not available to the ventilation protocols because of the following reasons: Patient participating in a different study (3 patients); and technical problems precluded protocol use (2 patients). An attending physician declined protocol use

[1]Corrected inspired tidal volume in milliliters per kilogram of average predicted body weight (from actuarial equations).

in 1 patient. Thus, of the 51 total ARDS patients, 46 were eligible for the protocols, 41 were available for protocol application, and 40 of the 41 available patients received mechanical ventilation by protocol.

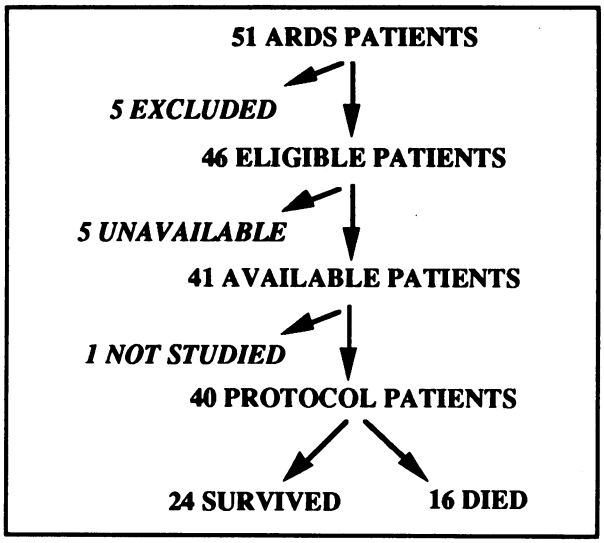

Figure 2. Flow of patients during the ventilation protocol study.

Sixteen of the patients treated by the ventilation protocols died, while 24 patients survived through the time of discharge from the hospital. Thus, the overall survival rate in ventilation protocol patients was 60%. We do not know of any complications attributable to our pH_a management style. Barotrauma rates seemed subjectively to be diminished in response to smaller tidal volumes, although we did not conduct a formal study of barotrauma rates.

We applied the ventilation protocols for a total of 10,903 hours in the 40 protocol patients. Of the total protocol application time, the protocols were suspended for only 568 hours (5% of the total time). The average duration of a protocol suspension was 2.5 hours. The clinical reasons for protocol suspension, along with the number of instances for each type of suspension, were:

Reasons for Protocol Suspensions	number
Patient undergoing a procedure or surgery	106
Problem with computer, software, or ventilator	76
Attending physician request	28
Unspecified transient patient problem	13

During operational time (protocols not suspended) the protocols generated a total of 3,148 instructions for tidal volume, ventilator rate, and I:E ratio or peak flow. The clinical staff followed 2,932 of the 3,148 instructions (93%). The reasons the clinical staff declined to follow 7% of protocol instructions and the number of instances for each reason were:

Reasons for Declining Protocol Instructions	number
Patient data not correct or current	63
Computer software error	45
Protocol error suspected by the clinical staff	31
Error in the protocol logic	22
Reason unknown	22
Staff was too busy to follow protocol instructions	11
Research staff testing the protocol software	10
Physician objection to a protocol instruction	8
Patient medically unstable	4

DISCUSSION

The most important requirement of a clinical decision support system is that it ensure patient safety. We have addressed this requirement by operating our system in an open-loop fashion, with every protocol instruction examined and subsequently implemented by the clinical (non-research) staff of our intensive care unit. If the clinical staff believed that a protocol instruction was incorrect or potentially harmful, they declined to follow that instruction. The 31 instructions the clinical staff declined to follow because of suspected protocol errors emphasizes their vigilance for patient safety. Even though these instructions were correct, the clinical staff rejected any instructions that they considered to be suspect or potentially harmful. They also correctly rejected faulty instructions due to software errors (45 instructions) and protocol logic errors (22 instructions).

A group of ARDS patients similar to our patients was reported to have a survival rate of 35% [9]. Our higher survival rate suggests that our system did not compromise patient safety, and might even have been favorable for patient outcome. However, a controlled study will be necessary to evaluate directly the effect of our system on patient outcome.

In our experience, practical clinical support tools must be actively developed in the clinical environment. We have found that the recommendation of an expert clinician regarding a hypothetical problem is often different from the same expert's recommendation regarding a particular patient problem. Active development in the clinical environment unites two key elements: First, a clinician must explicitly articulate his or her methods of patient management. Second, clinical application of the proposed method provides performance data that facilitates iterative refinement of that method. We believe that it is the combination of these two elements that allows devel-

opment of clinically *practical* decision support systems.

The ultimate test of practicality of a clinical support system is whether the system is in routine clinical use. A number of previously described ventilator management systems may have theoretical advantages in comparison to our system, but few are in routine clinical use. For example, the SIMV system developed in part by one of us (G. Thomsen) incorporates considerations about patient-specific lung physiology in determining the effects of ventilator changes [10]. However, this system, which was not developed in a clinical environment, has yet to see routine clinical application. In contrast, the ventilation protocols reported herein have achieved routine clinical use.

While the underlying principles of the ventilation protocols are relatively simple, it is not simple to implement a clinically robust system that accounts for patient, staff, and equipment variations. For example, we expended considerable effort to insure that ventilators made by different companies always delivered the tidal volume intended by the protocols. The clinical staff required a system that was easy to use and that allowed correction of data errors. The protocols had to be flexible enough to account for normal patient variations while remaining rigid enough to provide precise ventilation instructions. A lack of attention to these logistic and implementation details would have rendered the protocols difficult or perhaps dangerous to use. We found protocol development to be complex, requiring the coordination of team members having expertise in a variety of clinical and research areas.

Some members of the clinical staff found the protocols difficult to understand. A large share of this difficulty seemed to stem from implementation details rather than from complexity in the basic protocol strategy. To address this problem, we developed a variety of educational materials for the clinical staff. By focusing on the underlying principles of the protocols, these materials were largely successful in clarifying protocol operation.

In the past year, the ventilation protocols have achieved routine clinical use in our respiratory intensive care unit. The combination of the previously developed oxygenation protocols and the new ventilation protocols constituted a complete decision support system for ventilator management. Our results demonstrate that the ventilation protocols provided a practical and safe decision support system for the mechanical ventilation of critically-ill ARDS patients.

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